T.D

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,867	12/09/2003	Carl D. Wahlstrand	1023-336US01	6722

28863 7590 02/27/2006

SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,867	WAHLSTRAND ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/05, 02/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on December 12, 2005. No Claims have been withdrawn or cancelled. Claims 28 and 29 have been added. Claims 1-29 are pending.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on September 29, 2005 and February 3, 2006 have been acknowledged and are being considered by the Examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-2, 4-6, 10-11, 13-15, 17-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (U.S. 6,128,538) (herein Fischell). As to Claim 1, Fischell discloses an implantable system 10 for the treatment of neurological disorders as it would be situated under the scalp of a human head 9 having an implanted control module, read as an implantable medical device 20 (see Fischell Fig. 1 and column 11, lines 18-21). An embodiment of the implantable medical device 620 depicted in Fischell Fig. 21 shows that the device 920 comprises a plurality of interconnected modules including electronics module 626 and battery 625. The Examiner takes the position that the black lines outlining electronics module 626 and battery 625

in Fig. 21 depict a respective two of a plurality of housings. In addition, it is inherent that both an electronics module and a battery used in an implantable medical device such as device 620 have some sort of housings encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery fluid leakage (see Fischell Fig. 21). The embodiment of the implantable medical device 620 depicted in Fischell Fig. 21 also shows that the device 620 comprises an overmold 621, 624 which at least partially encapsulate each of the housings of the electronics module 626 and battery 625 and which is formed such that a surface of the overmold 621, 624 that is proximate to a cranium of a patient when the implantable medical device 620 is implanted on the cranium is concave along at least one axis prior to manipulation of the device (see Fischell Fig. 21 and column 29, lines 28-66).

5. As to Claim 2, Fischell also discloses that when the implantable medical device 620 is implanted on the cranium a surface of the overmold 621, 624 is concave along two axes (see Fischell Fig. 21).

6. As to Claim 4, Fishcell discloses that the overmold 621, 624 may be manufactured using a silicone adhesive to hold the overmold together (see Fischell column 29, lines 45-50). The Examiner thus takes the position that at least a portion of the overmold 621, 624 of the implantable medical device 620 of Fischell comprises silicone.

7. As to Claim 5, Fischell discloses that the overmold comprises at least two materials: top plate 624 and base 621 (see Fischell Fig. 21 and column 29, lines 28-66).

8. As to Claim 6, it is apparent from Fischell Fig. 21 that a surface of the overmold 621, 624 is concave such that the surface conforms substantially to the cranium (see Fischell Fig. 21).

9. As to Claim 10, the Examiner takes the position that the modules (i.e. electronics module 626 and battery 625) are positioned within the overmold 621, 624 of the implantable medical device 620 in a linear configuration (adjacent to each other) and makes reference to Fischell Fig. 21.

10. As to Claim 11, Fischell discloses that the overmold 621, 624 of the implantable medical device 620 completely encapsulates each of the modules (i.e. electronics module 626 and battery 625) and that a fluid seal is provided between the two surfaces 621, 624 (see Fischell Fig. 21 and column 29, lines 45-50).

11. As to Claim 13, in reference to Fig. 21 of Fischell the Examiner takes the position that the housing of each of the modules (both electronics module 626 and battery 625) comprises a surface that is" proximate to a cranium" when the implantable medical device 620 is implanted on the cranium. In addition, in Fig. 21 of Fischell both the electronics module 626 and the battery 625 are depicted to have at least one surface of the housings concave along at least one axis (see Fischell Fig. 21).

12. As to Claim 14, Fischell discloses that the implantable medical device 620 comprises an electronics module, read as a control module 626 that includes control electronics and in reference to Fischell Fig. 21 the surface of the housing of the control module 626 is concave along two axes (see Fischell Fig. 21, column 12, lines 3-54 and column 29, lines 45-50).

13. As to Claim 15, Fischell discloses that the implantable medical device 620 comprises a battery, read as a power source module 625 that in one embodiment includes a battery with a wound coil construction 635 and the surface of the housing of the power source module 625 and the would coil battery 635 are concave along one axis (see Fischell Figs. 17-19). In another

alternate embodiment, Fischell discloses that the power source module 625 within the implantable medical device 620 may also comprise a wound wire coil (see Fischell column 12, lines 55-67).

14. As to Claim 17, Fischell discloses that the implantable medical device 620 comprises a battery, read as a recharge module 625 that in one embodiment includes a battery with a wound coil construction 635 and the surface of the housing of the power source module 625 and the would coil battery 635 are concave along two axes (see Fischell Figs. 17-19).

15. As to Claim 18, it is apparent from Fischell Fig. 21 that a surface of the housings are concave such that the surfaces conform substantially to the cranium (see Fischell Fig. 21).

16. As to Claim 22, Fischell discloses that the implantable medical device 620 comprises a stimulation sub-system, read as a therapy delivery circuit 40 to deliver stimulation to the brain via electrodes 15 and wires 16 and control electronics 51 to control the delivery of stimulation by the therapy delivery circuit 40 where the therapy delivery circuit and control electronics 51 are located within the electronics module 626 (see Fischell Figs. 2-3 and 21, column 11, lines 21-22 and column 12, lines 3-54).

17. Claims 1-6, 11 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Bardy et al. (U.S. 6,788,974) (herein Bardy). As to Claim 1, Bardy discloses an implantable medical device (S-ICD or US-ICD) comprising a battery supply, capacitor and operational circuitry (see Bardy column 5, lines 10-18 and column 14, lines 42-45). It is inherent that a battery supply, capacitor and operational circuitry used in an implantable medical device have some sort of housings hermetically encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery or

capacitor fluid leakage. Bardy further discloses that the canister 190 of the implantable medical device (S-ICD or US-ICD) comprises a hermetically sealed housing, read as an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-20, the overmold 192 of the canister 190 is depicted as having a surface that is concave along at least one axis (see Bardy Figs. 19-20 and column 14, lines 18-37). The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The structure of the implantable medical device (S-ICD or US-ICD) of Brady is capable of being placed subcutaneously anywhere on a body and therefore meets the limitations presented in Claim 1.

18. As to Claim 2, the Examiner makes reference to Bardy Figs. 19-20 where the overmold 192 of the canister 190 is depicted as having a surface that is concave along at least two axes (see Bardy Figs. 19-20 and column 14, lines 18-37).

19. As to Claim 3, Bardy discloses that it is preferable to make the device have a "malleable canister", read as a "malleable overmold" that can conform to the desired shape of the implantation site on a patient (see Bardy column 6, lines 39-45). The Examiner takes the position that a "malleable overmold" is synonymous with an overmold that is "flexible".

20. As to Claim 4, Bardy discloses that the overmold 192 of the canister 190 may comprise silicone (see Bardy column 16, lines 31-35).

21. As to Claim 5, Bardy discloses that the overmold 192 of the canister 190 may comprise at least two materials (see Bardy column 16, lines 35-48).

22. As to Claim 6, Bardy discloses that it is preferable to make the device have a "malleable canister", read as a "malleable overmold" that can conform to the desired shape of the implantation site on a patient (see Bardy column 6, lines 39-45). The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The structure of the implantable medical device (S-ICD or US-ICD) of Brady is capable of being placed subcutaneously anywhere on a body and therefore meets the limitations presented in Claim 6.

23. As to Claim 11, it is apparent from Bardy Figs. 19-20 that the overmold 192 of the canister 190 completely encapsulates each of the modules (i.e. battery supply, capacitor and operational circuitry) (see Bardy Figs. 19-20).

24. Claim 22 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bardy. Bardy discloses that the implantable medical device (S-ICD or US-ICD) comprises a therapy delivery circuit (cardioversion/defibrillation or pacing) to deliver stimulation (see Bardy column 5, lines 26-44). It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made the pacing/cardioversion/defibrillation therapies are controlled by control electronics located in a hermetically sealed module within a housing or casing or overmold of an implantable medical device to mechanically and electronically isolate the control electronics from the battery, capacitors, sense/pace/shock channels or any other components of the device.

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. Claims 7-9, 19-21 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell. As to Claims 7 and 19, the Examiner takes the position that in Fischell Fig. 21, the overmold 621, 624 is concave such that the overmold conforms substantially to an arc (see Fischell Fig. 21). Fischell discloses the claimed invention as discussed above except that a radius of the arc is not specified to be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc of the concave overmold range from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

27. As to Claims 8 and 20, Fischell discloses the claimed invention as discussed above except that a radius of the arc is not specified to be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc of the concave overmold approximately equal to 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

28. As to Claims 9 and 21, Fischell discloses that the surface comprises a first surface of the overmold 621 and a second surface of the overmold 624 that is distal from the cranium when the

implantable medical device 620 is implanted on the cranium substantially conforms to the arc prior to manipulation of the medical device (see Fischell Fig. 21).

29. As to Claim 28, Fischell discloses the claimed invention as discussed above except that at least two of the housings of the modules are not specified to be metallic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the housings of each of the modules metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter or obvious design choice.

30. As to Claim 29, it is inherent that both an electronics module and a battery used in an implantable medical device such as device 620 have some sort of hermetic housings encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery fluid leakage (see Fischell Fig. 21). Fischell discloses the claimed invention as discussed above except that at least two of the housings of the modules are not specified to be formed of titanium or stainless steel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the housings of each of the modules titanium or stainless steel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter or obvious design choice.

31. As to Claim 23, Fischell discloses an implantable system 10 for the treatment of neurological disorders as it would be situated under the scalp of a human head 9 having an implanted control module, read as an implantable medical device 20 (see Fischell Fig. 1 and column 11, lines 18-21). The embodiment of the implantable medical device 620 depicted in

Fischell Fig. 21 also shows that the device 620 comprises a metallic housing 621, 624 that includes a surface that is proximate to a cranium of a patient when the implantable medical device 620 is implanted on the cranium which is concave along at least one axis such that the surface conforms substantially to an arc (see Fischell Fig. 21 and column 29, lines 28-66). Fischell discloses the claimed invention as discussed above except that a radius of the arc is not specified to be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc of the concave housing to be within a range from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

32. As to Claim 24, Fischell discloses the claimed invention as discussed above except that a radius of the arc is not specified to be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc of the concave housing approximately equal to 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

33. As to Claim 25, Fischell also discloses that when the implantable medical device 620 is implanted on the cranium a surface of the housing 621, 624 is concave along two axes (see Fischell Fig. 21).

34. As to Claim 26, Fischell discloses that the surface comprises a first surface of the housing 621 and a second surface of the housing 624 that is distal from the cranium when the implantable medical device 620 is implanted on the cranium substantially conforms to the arc prior to manipulation of the medical device (see Fischell Fig. 21).

35. As to Claim 27, Fischell discloses that the implantable medical device 620 comprises a stimulation sub-system, read as a therapy delivery circuit 40 to deliver stimulation to the brain via electrodes 15 and wires 16 and control electronics 51 to control the delivery of stimulation by the therapy delivery circuit 40 where the therapy delivery circuit and control electronics 51 are located within the electronics module 626 (see Fischell Figs. 2-3 and 21, column 11, lines 21-22 and column 12, lines 3-54).

36. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell in view of Faltys et al. (U.S. 6,308,101) (herein Faltys). Fischell discloses the claimed invention as discussed above except that the overmold does not not encapsulate a portion of each of the modules that is proximate to a cranium of a patient when the implantable medical device is implanted on the cranium.

Faltys, however, discloses an implantable medical device 170 comprising a plurality of interconnected modules, speech processor 210 and stimulator 212 (see Faltys Abstract, lines 1-4) and a silicone rubber overmold 174 that at least partially encapsulates each of the equivalent speech processor 162 and equivalent stimulator 112' (see Faltys Figs. 3A and 3B and column 12, line 39). Faltys also discloses that the plurality of interconnected modules are contained in separate, implantable, hermetically sealed cases (see Faltys column 23, lines 12-14). Overmold 174 of Faltys does not encapsulate a portion of each of the modules that is proximate to a cranium of a patient when the implanted medical device is implanted on the cranium (see Faltys Figs. 3A and 3B). The Examiner takes the position that the device of Faltys Figs. 3A and 3B is implanted so that the bottom of Fig. 3A is proximate to the cranium of a patient when implanted on the cranium and the top of Fig. 3A, comprising the overmold 174, is distal to the cranium of a

patient when implanted on the cranium. The Examiner also takes the position that both the device of Fischell and the device of Faltys are synonymous because they are both implantable medical devices meant for subcutaneous implantation on the cranium. Faltys does not explicitly state why such an overmold 174 is used, but it appears that such an overmold is used to provide a thinner implantable device that takes up less space and would not significantly protrude from any implantation site on the skull. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Fischell, with the partially encapsulating overmold of 174 as taught by Faltys, since such a modification would provide the device with a thinner profile for providing a more comfortable and easier to implant device.

37. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell in view Berrang et al. (U.S. 3,358,281) (herein Berrang). Fischell discloses the claimed invention as discussed above except that the power source module 625 does not include a battery with a foil pack construction.

Berrang, however, discloses an implantable medical device 1 comprised of three interconnected modules 2, 3, and 4, modules 2 and 3 each contained within a housing, and connector bridge 6 that at least partially encapsulates each of the modules (see Berrang Fig. 1). Connector bridge 6 is adapted to allowing the surgeon to better fit the housing sections 2 and 3 to the curvature of the implantee's skull (see Berrang column 9, lines 55-56). Berrang also discloses a module that is a power source module including a battery (see Berrang column 4, lines 32-34) within a housing that is mounted on an insulated substrate further bonded to an underlying gold foil substrate (see Berrang column 3, lines 38-39 and lines 49-50) to provide biocompatibility and pliability (see Berrang column 16, lines 40-45). The Examiner also takes

the position that both the device of Fischell and the device of Berrang are synonymous because they are both implantable medical devices meant for subcutaneous implantation on the cranium. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Fischell in view and Berrang to include a power source module that includes a battery with a foil pack construction to provide enhanced biocompatibility and pliability of the power source.

38. Claims 7-9 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy. As to Claim 7, the Examiner takes the position that in Bardy Figs. 21, the overmold 192 of the canister 190 is concave such that the overmold 192 conforms substantially to an arc (see Bardy Figs. 19-21). Bardy discloses the claimed invention as discussed above except that a radius of the arc is not specified to be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc of the concave overmold range from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

39. As to Claim 8, Bardy discloses the claimed invention as discussed above except that a radius of the arc is not specified to be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc of the concave overmold approximately equal to 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

40. As to Claim 9, Bardy discloses the overmold 192 of the canister 190 may comprise a first surface 196 and a second surface 194 distal from the implantation site when the implantable

device canister 190 is implanted conforming to an arc (see Bardy Fig. 19 and column 17, lines 36-44).

41. As to Claim 28, Bardy discloses the claimed invention as discussed above except that at least two of the housings of the modules are not specified to be metallic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the housings of each of the modules metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter or obvious design choice.

42. As to Claim 29, it is inherent that a battery supply, capacitor and operational circuitry used in an implantable medical device have some sort of hermetic housings encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery fluid leakage. Bardy discloses the claimed invention as discussed above except that at least two of the housings of the modules are not specified to be formed of titanium or stainless steel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the housings of each of the modules titanium or stainless steel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter or obvious design choice.

43. As to Claim 23, Bardy discloses an implantable medical device (S-ICD or US-ICD) comprising a battery supply, capacitor and operational circuitry (see Bardy column 5, lines 10-18 and column 14, lines 42-45) and a hermetically sealed housing 192 that includes a surface that is concave along at least on axis (see Bardy Figs. 19-21 and column 14, lines 6-49). The Examiner

notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The structure of the implantable medical device (S-ICD or US-ICD) of Brady is capable of being placed subcutaneously anywhere on a body and therefore meets the limitations presented in Claim 23. Bardy disclose the claimed invention as discussed above except that a radius of the arc of at least one surface of the housing 192 is not specified to be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc of the concave housing 192 range from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art.

44. As to Claim 24, Bardy discloses the claimed invention as discussed above except that a radius of the arc is not specified to be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc of the concave overmold approximately equal to 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

45. As to Claim 25, the Examiner makes reference to Bardy Figs. 19-20 where the housing 192 of the canister 190 is depicted as having a surface that is concave along at least two axes (see Bardy Figs. 19-20 and column 14, lines 18-37).

46. As to Claim 26, Bardy discloses the overmold 192 of the canister 190 may comprise a first surface 196 and a second surface 194 distal from the implantation site when the implantable

device canister 190 is implanted conforming to an arc (see Bardy Fig. 19 and column 17, lines 36-44).

47. As to Claim 27, Bardy discloses that the implantable medical device (S-ICD or US-ICD) comprises a therapy delivery circuit (cardioversion/defibrillation or pacing) to deliver stimulation (see Bardy column 5, lines 26-44). It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made the pacing/cardioversion/defibrillation therapies are controlled by control electronics located in a hermetically sealed module within a housing or casing or overmold of an implantable medical device to mechanically and electronically isolate the control electronics from the battery, capacitors, sense/pace/shock channels or any other components of the device.

Double Patenting

48. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

49. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 11-15, 18, 20-30, 35-49, 51 and 53-55 of copending Application No. 10/731, 869. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

50. Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 12-14, 18-22, 31-35, 39-43 and 45-49 of copending Application No. 10/730,873. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

51. Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

52. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kirkpatrick et al. (U.S. 6,480,743) teaches that it is well known in the art to manufacture an intracranially implanted device to conform substantially to the shape of a cranium.

Meltzer (U.S. 5,645,586) discloses a conforming implantable device comprising at least a first module that includes control electronics within a first housing and a second module that includes a second housing and an overmold that at least partially encapsulates the first and second housings.

Muto (U.s. 4,094,321) discloses a dome-shaped pacemaker to avoid infection, irritation or rejection caused by sharp corner edges protruding from an implant.

Sanchez-Zambrano (U.s. 5,895,414) discloses a pacemaker with an anatomically shaped housing (i.e. a concave inner wall and a convex outer wall) for fitting smoothly under the skin.

53. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

54. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 02/21/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766